Cancer Action Network℠
American Cancer Society®

Clinical Trials

Primer

Clinical trials are essential gateways to developing better tools for cancer prevention, detection, treatment and care. The research conducted through clinical trials helps move scientific discoveries from the laboratory into new therapies that can be used at the bedside to improve the quality of patient care. Yet consistently low enrollment of adults in clinical trials, particularly among racial and ethnic minority groups and low income groups, delays our progress.

Only 3-5% of adult cancer patients participate in clinical trials each year. This slows the pipeline for bringing new cancer advances to patients.

What is a clinical trial?

A clinical trial is a research study that answers specific questions about the safety and effectiveness of new drugs and treatments developed to address serious illness like cancer. Carefully conducted clinical trials are the fastest and safest way to find new vaccines, early detection tests, treatments, and therapies that support improved quality of life. There are no placebos in clinical trials for cancer treatment. Typically, researchers use trials to compare a new approach or agent to the most effective, standard therapy. Clinical trials may take place at a local hospital, university, cancer center, military or veteran's hospital, or even a physician's office.

Who sponsors clinical trials?

There are many different potential sponsors of clinical trials, including the federal government and drug or medical device companies. Many different agencies within the federal government such as the National Institutes of Health, the National Cancer Institute, and the Department of Veteran Affairs sponsor clinical trials.

Who is eligible for a clinical trial?

Each clinical trial has established protocols that identify patient eligibility requirements, all of which depend on the purpose of the particular study. Patients whose standard therapy is ineffective or patients for whom standard therapy may induce serious health risks may wish to seek treatment in a clinical trial.

Who pays for a clinical trial?

The trial sponsor (e.g., a drug company) generally pays for the investigational drug/treatment and any research-related costs such as data collection and analysis. Therefore, the only portion of the clinical trial that is not paid for by the sponsor is patient care costs—the costs for the care that a patient would receive whether they were receiving standard care or care provided through a clinical trial. Insurance coverage for patient care costs in clinical trials varies considerably across the country.

Why do so few patients enroll in clinical trials?

While about 20% of cancer patients in any given year meet eligibility requirements for participation in active clinical trials, fewer than 5% of all adult cancer patients actually enroll in a clinical trial. People with low income, the elderly, racial/ethnic minorities, women, and those living in rural areas represent the smallest percentage of clinical trials participants.

Many barriers to trials participation have been identified, including:

- Concerns about health insurance coverage for patient care costs in clinical trials
- Insufficient information, education and outreach directed toward healthcare professionals and their patients regarding the availability and location of cancer clinical studies
- Patient or family misunderstanding or fear about participating in a clinical trial
- Doctor does not recommend clinical trial participation to patient

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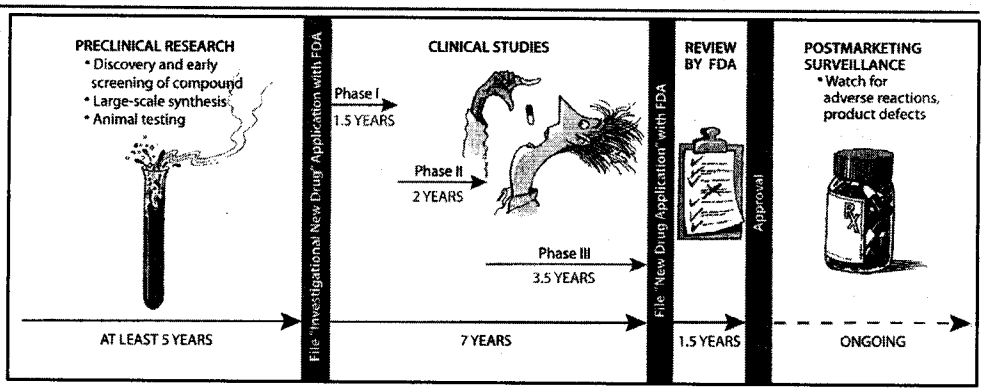
What is the clinical trials process?

Traditionally, there are four phases of clinical trials. In phases one through three, the clinical trial enrolls progressively more participants—phase one trials involve only a handful of participants while phase three trials may involve thousands of individuals at multiple trials sites. New drugs or treatments must progress through each phase to establish safety and efficacy before they can be approved for broad use in the market. The fourth phase of a clinical trial takes place after the new drug or treatment has been released to the general public to continue monitoring the product and its effects in the broader population.



Are there different types of clinical trials?

Yes. There are four main types of cancer clinical trials: prevention, detection, treatment, and those focused on symptom management and other aspects of care supporting quality-of-life. Prevention trials are designed to evaluate cancer-causing behavior or anti-cancer development. Detection trials test new methods for detecting cancer in the disease's earliest stage. Treatment trials, the most common type of cancer clinical trial, test new and emerging therapies for cancer patients. Lastly, quality-of-life trials look at ways to increase the comfort and well-being of cancer patients.

How can patients find the right clinical trial for them?

They can contact the American Cancer Society at 1-800-ACS-2345 or by visiting www.cancer.org to get assistance in finding trials for which they may be eligible through its clinical trials matching service. The Society and the Coalition of Cancer Cooperative Groups joined forces to provide information to patients seeking clinical trials. After providing some demographic, clinical, and geographic information, the Society can provide information about available trials.

Why are some patients afraid of participating in a clinical trial?

One huge misconception about cancer clinical trials is that trial participants are treated like "guinea pigs." This is not true. Just as with standard care, individuals may have side effects or experience complications from treatments in trials, but great care and consideration goes into the health and safety of clinical trial participants in trial design and implementation. Participants also may drop out of the study at any time if they chose to do so.

Sponsors of clinical trials are monitored by several federal agencies to ensure participant safety, including the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Trials are monitored closely at all times. For example, each Phase III trial is required to have a Data Safety Monitoring Board, which has the power to prematurely terminate a trial should the experimental therapy prove more effective than the standard therapy, or alternatively halt the trial immediately if significant adverse events arise. Each trial is responsible for meeting the Code of Federal Regulations for the Protection of Human Subjects and ensuring the safety of clinical trial participants. In order to do this, the trial must receive approval from an institutional review board (IRB).

How has clinical trial research help us win the cancer fight?

Cancer clinical trials have been dramatically successful in delivering progress for childhood cancer survival rates. Since 1960, mortality rates for all children with cancer have decreased 62%. Specifically, the survival rate for children with acute lymphocytic leukemia, the most common leukemia in children, has increased from 4% to approximately 80%.